PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 31/00 — A1

(11) International Publication Number: WO 98/33547

(43) International Publication Date: 6 August 1998 (06.08.98)

(21) International Application Number: PCT/US98/01844

(22) International Filing Date: 29 January 1998 (29.01.98)

(30) Priority Data:
60/036,317 30 January 1997 (30.01.97) US

(71) Applicant: MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH [US/US]; 200 First Street S.W., Rochester, MN 55905 (US).

(72) Inventors: BROWN, David, L.; 3300 Fox Hollow Court S.W., Rochester, MN 55902 (US). CAHILL, Donald, R.; 1919-6th Avenue N.E., Rochester, MN 55904 (US).

(74) Agent: ELLINGER, Mark, S.; Fish & Richardson P.C., P.A., Suite 3300, 60 South Sixth Street, Minneapolis, MN 55402 (US).

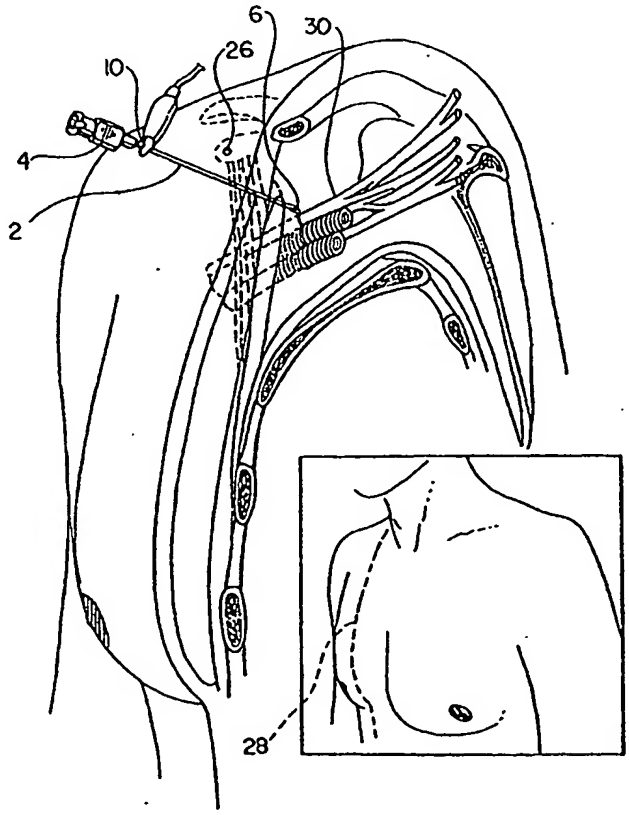
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PERIPHERAL NERVE SITE ANESTHESIA

(57) Abstract

The invention relates to a needle-catheter assembly and methods for administering anesthetic to a peripheral nerve site in a patient. The assembly includes a nerve stimulator needle (2) and a catheter (12) including a nerve stimulator lead.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

TITLE OF THE INVENTION

PERIPHERAL NERVE SITE ANESTHESIA

Cross Reference To Related Application

This application claims priority from U.S. Provisional Application Serial No. 60/036,317, filed January 30, 1997.

Background of the Invention

Continuous brachial plexus analgesia is a pain relief technique that is useful in caring for patients undergoing specific types of upper extremity surgery and in caring for selected patients with upper extremity pain syndromes. Each year in the United States over 400,000 patients undergo upper extremity surgical procedures. Detailed Diagnosis and Procedures, National Hospital Discharge Survey, 1993. Vital Health Statistics, Series 13, No. 122. H.S. Department of Health and Human Services, Public Health Service, National Center for Health Statistics, October 1995. DHHS Publications No. (PHS) 95-1783. It is estimated that 10-20% of these patients may be candidates for prolonged upper extremity analgesia produced by local anesthetic infusions. It is also estimated that 3-7% of chronic pain clinic patients in the U.S.A. experience upper extremity chronic pain syndromes each year. Abram, Reflex Sympathetic Dystrophy: Incidence and Epidemiology, In: Stanton-Hicks et al. (eds): Reflex Sympathetic Dystrophy. Kluwer Academic Publishers, Boston, 1990, pp. 9-16. Approximately 10% of these patients may be candidates for brachial plexus continuous infusion analgesia techniques. The number of chronic pain patients to which continuous infusion techniques may be applied is also significant.

Patients undergoing major elbow, wrist or shoulder surgeries are frequently placed into continuous passive motion (CPM) devices that continuously move a joint through its range-of-motion. This is carried out to produce better functional results from these upper extremity joint surgeries. As a result of using CPM devices, pain relief can be a problem due to the constant stimulation of pain (nociceptive) pathways.

One option in providing analgesia in these patients is to continuously infuse a local anesthetic near the brachial plexus via a percutaneously inserted catheter. Continuous brachial plexus analgesia is an accepted pain relief technique following upper extremity surgery. Kobayashi and Murakami Can. Anaesth. Soc. J. 30:201-205 (1983). Typically, the catheter is inserted after a needle is placed near the brachial plexus using an electronic nerve stimulator to guide needle insertion. Gaumann et al., Reg. Anesth. 13:77-82 (1988). The regional block sites chosen for catheter insertion range from axillary to infraclavicular to supraclavicular to interscalene. Urmey, Upper Extremity Blocks, In: Brown DL (ed): Regional Anesthesia and Analgesia, W.B. Saunders Co., Philadelphia, 1996, pp. 254-278. There are currently two major drawbacks to these present methods: first, once the catheter is inserted beyond the needle tip there is no way to assure proximity to the brachial plexus; and second, over time the percutaneously placed catheters have a tendency to be dislodged from their original positions.

Once a nerve stimulator needle is placed in proximity to the brachial plexus a catheter is threaded for 5 to 10 cm. through the needle. Gaumann et al., Reg. Anesth. 13:77-82 (1988). Insertion of this relatively short length of catheter facilitates placement of the

catheter near the brachial plexus. This advantage must be balanced, however, by the fact that inserting longer lengths of catheter is more advantageous for preventing dislodgement from the brachial plexus site. Although needle placement near the brachial plexus is assured by observing upper extremity movement (motor response) to the electric nerve stimulation, there currently is no way to electronically verify correct catheter placement once it is inserted via the needle.

Presently, to verify correct catheter position, anesthesiologists must inject local anesthetic via the brachial plexus catheters and then wait for the biologic effect, i.e., the expected sensory-motor changes. It may take from 30 to 45 minutes for sufficient time to pass to allow assessment of clinically appropriate catheter position near the brachial plexus using this technique. This delay in positively identifying catheter position can lead to periods of ineffective analgesia since, if the catheter is deemed to be out of position, another catheter needs to be inserted and the process repeated. Patients and physicians would benefit from a more direct and efficient method of catheter placement.

Another improvement needed in the brachial plexus catheter is a better method of securing the catheter once correct position is originally identified. Brachial plexus catheter dislodgement during the course of a three to four day postoperative analgesia regimen is frequent. This is especially so when axillary, supraclavicular and interscalene sites are used, and less so when an infraclavicular site is used. Urmey, Upper Extremity Blocks, In: Brown DL (ed): Regional Anesthesia and Analgesia, W.B. Saunders Co., Philadelphia, 1996, pp. 254-278. Necessary movement of the involved upper extremity contributes to these catheter dislodgements.

Typically the catheters are secured only at the skin with either an adhesive dressing or skin suture, and even if the catheter remains secured at the skin dislodgement from a location near the brachial plexus can still occur.

Summary of the Invention

The invention includes a new needle-catheter assembly device and method of percutaneously inserting, verifying, and securing a catheter near the brachial plexus and other peripheral nerve locations. The new device and technique is designed to address the two primary problems of current techniques, i.e., initial catheter misplacement and dislodgement of the catheter over time.

In general, the invention features a kit for administering anesthetic to a peripheral nerve site in a patient. The kit includes a nerve stimulator needle having a shaft and a lumen through the shaft, and a catheter having a proximal portion and a distal portion. The catheter includes a nerve stimulator lead at the distal portion, and the proximal portion is adapted for attachment to a nerve stimulator electrode. The catheter is adapted for passage through the lumen of the nerve stimulator needle shaft. The catheter can further include a balloon and a lumen for inflating the balloon.

In another aspect, the invention features a method for administering analgesia to a peripheral nerve site in a patient. The method involves inserting a catheter into a nerve stimulator needle positioned within the patient. The catheter has a proximal portion and a distal portion, and the catheter includes a nerve stimulator lead located at the distal portion. The proximal portion of the catheter is attached to a nerve stimulator electrode. Once inserted into the patient, the catheter is advanced

into the peripheral nerve site while providing motor response-inducing current to the stimulator lead. Following this, the motor response of patient is monitored to determine appropriate placement of the distal portion of the catheter within the peripheral nerve site. Upon appropriate placement of the distal portion, anesthetic is administered to the peripheral nerve site.

In practicing the method of the invention, a catheter can be used that further includes a catheter immobilizing structure for immobilizing the catheter in the patient. For example, the catheter can include an inflatable balloon, a spring-activated expanding plate or other structure that can be used to immobilize the catheter in the patient after the catheter is correctly positioned. Typically, the anesthetic is administered continuously to the peripheral nerve site for a period of time appropriate to the patient's needs.

The needle-catheter assembly can be used in a new coracoid block technique to address the problems identified with current regional anesthesia practice. As described above, the needle-catheter assembly employs a stimulator needle, typically with a curved tip, combined with a nerve stimulator catheter to facilitate identifying correct catheter position near the brachial plexus even before local anesthetic is injected. The inflatable balloon optionally attached to the shaft of the catheter prevents deep dislodgement of the catheter from the pericoracoid location once positioned for the local anesthetic infusion. The invention is potentially applicable to 40,000 to 80,000 patients in the United States alone, even considering only candidates for upper extremity analgesia. The numbers are even larger considering the total number of candidates requiring

anesthesia at other peripheral nerve sites. The number of chronic pain patients to which the invention may be applied is also significant.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

Other features and advantages of the invention will be apparent from the following detailed description, and from the claims.

Brief Description of the Drawings

Fig. 1 is a schematic representation of placement of a needle of the invention in a patient undergoing a peri-coricoid block technique.

Fig. 2 is a schematic representation of placement of a needle of the invention in a patient undergoing a peri-coricoid block technique, with a catheter inserted in the needle.

Fig. 3 is a schematic representation of the patient depicted in Figs. 1 and 2, with the needle having been withdrawn and a catheter balloon having been inflated to prevent dislodgement.

Description of the Preferred Embodiments

Referring to Figure 1, the needle-catheter assembly includes a needle 2 appropriate for nerve stimulation and placement. Typically, the needle is a 3.5 to 5 inch (9 to 13 cm) 20-gauge curved-tipped, insulated shaft nerve stimulator needle, with the needle hub 4 marked to identify direction of bevel opening 6. The needle 2 is designed to accommodate attachment of a nerve stimulater electrode 8 to the proximal needle shaft 10. Referring to Figure 2, a catheter 12, typically a 22-gauge catheter (approximately 16 cm. in length), is designed with a distal catheter stimulator lead 14 placed near the catheter tip 16 and a proximal attachment for the nerve stimulator electrode 8 to connect to the catheter 12. The catheter may also have a balloon 20 attached at some point along the shaft 22 of the catheter 12, typically mid-shaft, and a separate lumen 24 within the catheter 12 to inflate the balloon 20.

As an example of the regional technique that can be used with this new device, the following procedures represent a peri-coracoid block that purposely inserts onto the coracoid process. The steps of the technique are:

1. The patient assumes the supine position with the upper extremity to be blocked placed along the patient's ipsilateral side.

2. Referring again to Figure 1, the ipsilateral coracoid process 26 is identified and marked with a surface skin marker.

3. A skin wheal of local anesthetic is placed about 2 cm caudad and about 2 cm medial to the coracoid process, and local anesthetic infiltration continued into the subcutaneous tissue.

4. Referring to Figure 1, the 20-gauge curved-tipped stimulator needle 2 is inserted in a posterior direction in the parasagittal plane 28 (inset of Figure 1). During insertion, the needle 2 is stimulated at 1 to 2 mA, and the needle 2 is redirected in the parasagittal plane 28 in small steps until distal ipsilateral upper extremity motor response is observed. The stimulator current is then decreased to <0.5 mA while observing for continued distal ipsilateral upper extremity motor response. The needle bevel is faced such that the bevel opening 6 is directed either proximally or distally along the brachial plexus 30 depending on the goal of catheter 12 placement.

5. Referring again to Figure 2, with the needle 2 held firmly in place the catheter 12 is attached to the nerve stimulator lead 8 and the catheter 12 advanced until 5 to 7 cm of catheter 12 exits the needle 2 and stimulation at <0.5 mA produces an appropriate upper extremity motor response. The needle 2 is then withdrawn over the catheter 12 and the catheter 12 again tested for correct placement via nerve stimulation at <0.5 mA.

6. Referring to Figure 3, following withdrawal of the needle 2, the catheter balloon 20 is inflated with air and the catheter snugged against the posterior surface of the pectoralis minor muscle tendon 32. The catheter 12 is again tested for correct placement via nerve stimulation at <0.5 mA after the catheter 12 is snugged against the tendon 32.

7. The catheter 12 is secured to the skin and a sterile dressing applied to the insertion site. An appropriate bolus of local anesthetic is injected via the catheter 12 and the continuous infusion begun.

The disclosed needle-catheter assembly device and method facilitates postoperative analgesia in upper

extremity surgical patients and other patients requiring peripheral nerve blocks. In addition to perioperative uses, the device will also be of benefit to outpatients, such as those with chronic pain syndromes. The device can be conveniently packaged as a kit including packaging material capable of maintaining sterility until opened. The nerve stimulator needle 2, catheter 12 and any ancillary materials can be separately housed, if desired, in the packaging material. The components of the kit can be sterilized before or after placement in the packaging material.

It is to be understood that while the invention has been described in conjunction with the foregoing detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.

Claims

What is claimed is:

1. A needle-catheter assembly for administering anesthetic to a peripheral nerve site in a patient, comprising

a) a nerve stimulator needle having a shaft and a lumen through said shaft; and

b) a catheter having a proximal portion and a distal portion, said catheter comprising a nerve stimulator lead at said distal portion, said proximal portion adapted for attachment to a nerve stimulator electrode, said catheter being housed within said lumen of said nerve stimulator needle shaft.

2. The needle-catheter assembly of claim 1, wherein said catheter further comprises a balloon and a lumen for inflating said balloon.

3. A kit for administering anesthetic to a peripheral nerve site in a patient, comprising

a) a nerve stimulator needle having a shaft and a lumen through said shaft; and

b) a catheter having a proximal portion and a distal portion, said catheter comprising a nerve stimulator lead at said distal portion, said proximal portion adapted for attachment to a nerve stimulator electrode, and said catheter adapted for passage through said lumen of said nerve stimulator needle shaft.

4. The kit of claim 3, wherein said catheter further comprises a balloon and a lumen for inflating said balloon.

5. A method for administering analgesia to a peripheral nerve site in a patient, comprising

a) inserting a catheter into a nerve stimulator needle positioned within said patient, said catheter having a proximal portion and a distal portion, said catheter comprising a nerve stimulator lead at said distal portion, said proximal portion attached to a nerve stimulator electrode,

b) advancing said catheter into said peripheral nerve site while providing motor response-inducing current to said stimulator lead;

c) monitoring motor response of said patient to determine appropriate placement of said distal portion of said catheter within said peripheral nerve site; and,

d) upon appropriate placement of said distal portion, administering anesthetic to said peripheral nerve site.

6. The method of claim 5, wherein said catheter further comprises an inflatable balloon adapted for immobilizing said catheter in said patient, and said anesthetic is administered continuously to said peripheral nerve site.

Fig.1

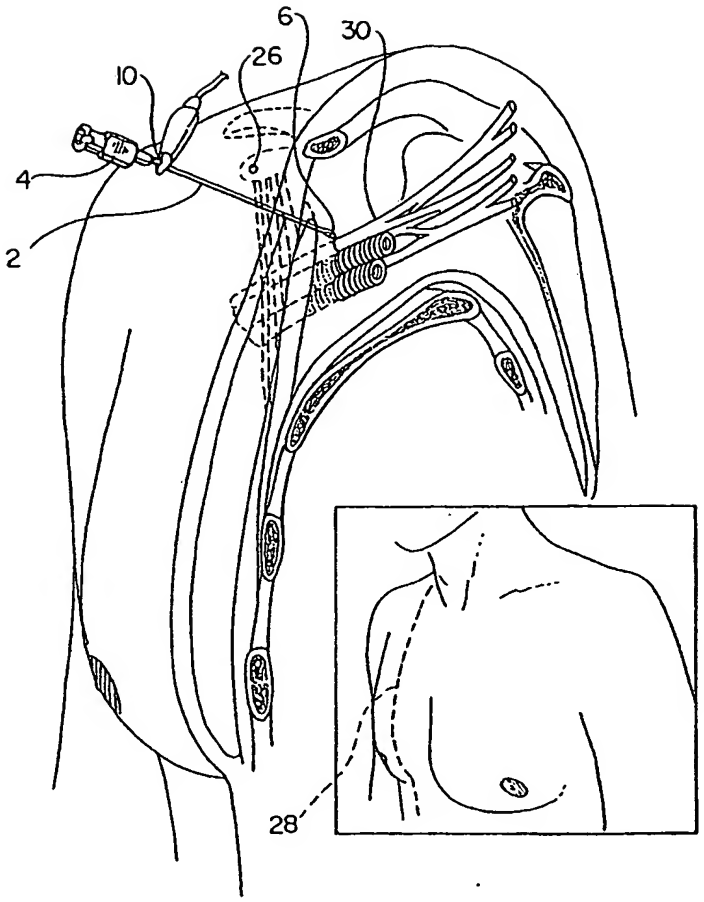


Fig.2

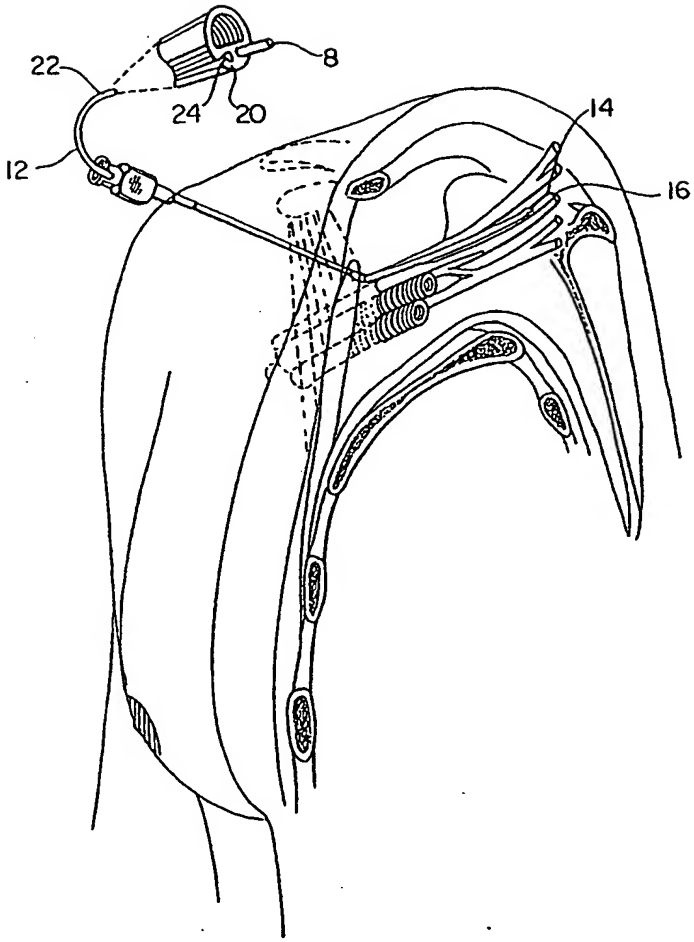
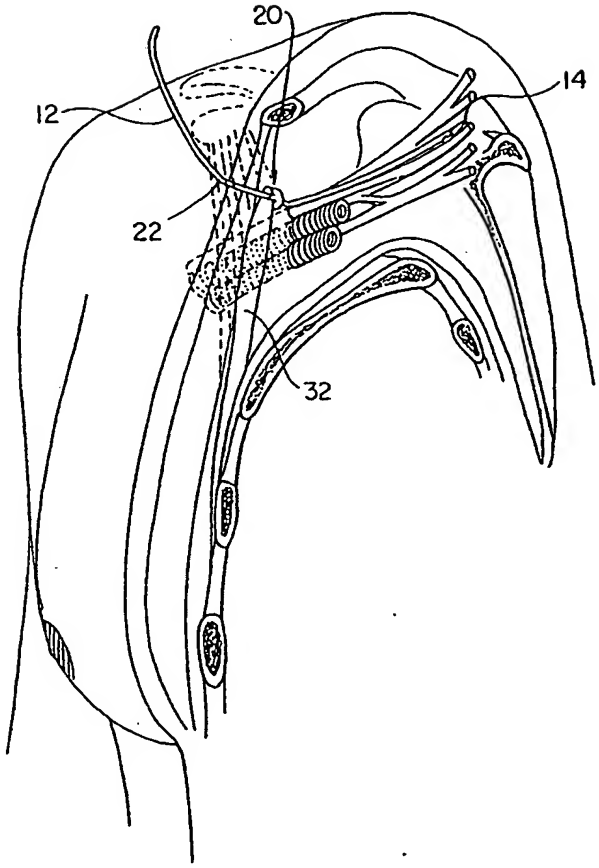


Fig.3



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01844

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 31/00
US CL :604/49

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/49

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,721,506 A (TEVES) 26 JANUARY 1988, ENTIRE PATENT.	1-6
Y	US 5,129,889 A (HAHN ET AL) 14 JULY 1992, ENTIRE PATENT.	1-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 22 JUNE 1998	Date of mailing of the international search report 17 JUL 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MANUEL MENDEZ Telephone No. (703) 308-2221

Form PCT/ISA/210 (second sheet)(July 1992)*